

Executive Registry

81-4170

29 April 1981

MEMORANDUM FOR: Director of Central Intelligence

VIA: Deputy Director of Central Intelligence
Deputy Director for Administration
25X1 Director of Medical Services

FROM: [REDACTED] DD/A REGISTRY
Agency Liaison Officer FILE: Pers-4
President's Commission for the Study
of Ethical Problems in Medicine and
Biomedical and Behavioral Research

SUBJECT: Agency Human Subject Research Panel (HSRP)

1. The purpose of this memorandum is to suggest activation of the Agency Human Subject Research Panel (HSRP) as provided in the 16 January 1981 revision of [REDACTED] (Attachment A) and to suggest membership on that Panel.

2. Executive Order 12036 (Attachment B) has set up restrictions on human experimentation except in accordance with guidelines issued by the Department of Health and Human Services. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research is the overall monitoring body for the Federal Government. This Commission was established in accordance with Public Law 95-622 (Attachment C). An Agency task force, organized in March 1980 by the Deputy Director for Administration (Attachment D), proposed modifications to [REDACTED] in supporting liaison with the Commission. This proposal included the establishment of the HSRP to review documentation and certification pertaining to such research sponsored by, contracted for, or conducted by the Agency.

3. Several Agency components recently have indicated that activities are planned which will require human participation. Therefore, the Agency needs to review documentation and certification to insure that the rights of the human subjects have been duly considered and are protected. The activation of the HSRP would be timely.

SUBJECT: Agency Human Subject Research Panel (HSRP)

4. In order to draw upon the experience of the Agency task force, I propose that representation from each major component be continued on the HSRP and, where possible, representatives who have served on that task force also serve on the HSRP. Further, I propose that the Panel be authorized to secure the advice of appropriate professional consultants so as to assist the Panel in its deliberations. I propose the following initial make-up of the Panel:

National Foreign Assessment Center - []	25X1
Directorate of Operations - []	25X1
Directorate of Science and Technology - (to be announced)	
General Counsel - []	25X1
Directorate of Administration (Chairman) - []	

25X1

(Signed)

[]

25X1

Attachments

APPROVED:

7s7 William J. Casey

Director of Central Intelligence

13 MAY 1981

Date

25X1 OMS/PD/[] (29Apr81)

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25X1

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THURSDAY, JANUARY 26, 1978
PART II



THE PRESIDENT

UNITED STATES INTELLIGENCE ACTIVITIES

Executive Order 12036

(d) Information needed solely to identify individuals in contact with those persons described in paragraph (c) of this section or with someone who is the subject of a lawful foreign intelligence or counterintelligence investigation;

(e) Information concerning persons who are reasonably believed to be potential sources or contacts, but only for the purpose of determining the suitability or credibility of such persons;

(f) Information constituting foreign intelligence or counterintelligence gathered abroad or from electronic surveillance conducted in compliance with Section 2-202 or from cooperating sources in the United States;

(g) Information about a person who is reasonably believed to be acting on behalf of a foreign power, engaging in international terrorist activities or narcotics production or trafficking, or endangering the safety of a person protected by the United States Secret Service or the Department of State;

(h) Information acquired by overhead reconnaissance not directed at specific United States persons;

(i) Information concerning United States persons abroad that is obtained in response to requests from the Department of State for support of its consular responsibilities relating to the welfare of those persons;

(j) Information collected, received, disseminated or stored by the FBI and necessary to fulfill its lawful investigative responsibilities; or

(k) Information concerning persons or activities that pose a clear threat to any facility or personnel of an agency within the Intelligence Community. Such information may be retained only by the agency threatened and, if appropriate, by the United States Secret Service and the FBI.

2-3. *Additional Restrictions and Limitations.*

2-301. *Tax Information.* No agency within the Intelligence Community shall examine tax returns or tax information except as permitted by applicable law.

2-302. *Restrictions on Experimentation.* No agency within the Intelligence Community shall sponsor, contract for, or conduct research on human subjects except in accordance with guidelines issued by the Department of Health, Education and Welfare. The subject's informed consent shall be documented as required by those guidelines.

2-303. *Restrictions on Contracting.* No agency within the Intelligence Community shall enter into a contract or arrangement for the provision of goods or services with private companies or institutions in the United States unless the agency sponsorship is known to the appropriate officials of the company or institution. In the case of any company or institution other than an academic institution, intelligence agency sponsorship may be concealed where it is determined, pursuant to procedures approved by the Attorney General, that such concealment is necessary to maintain essential cover or proprietary arrangements for authorized intelligence purposes.

2-304. *Restrictions on Personnel Assigned to Other Agencies.* An employee detailed to another agency within the federal government shall be responsible to the host agency and shall not report to the parent agency on the affairs of the host agency unless so directed by the host agency. The head of the host agency, and any successor, shall be informed of the employee's relationship with the parent agency.

2-305. *Prohibition on Assassination.* No person employed by or acting on behalf of the United States Government shall engage in, or conspire to engage in, assassination.

2-306. *Restrictions on Special Activities.* No component of the United States Government except an agency within the Intelligence Community may conduct any special activity. No such agency except the CIA (or the military services in wartime) may conduct any special activity unless the President determines, with

PUBLIC LAW 95-622—NOV. 9, 1978

"TITLE XVIII—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH"

"ESTABLISHMENT OF COMMISSION"

"SEC. 1801. (a) ESTABLISHMENT.—(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereinafter in this title referred to as the 'Commission') which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

"(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

"(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

"(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

"(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health, Education, and Welfare, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Administrator of Veterans' Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

"(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

"(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

"(b) TERMS.—(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

"(2) Of the members first appointed—

"(A) four shall be appointed for terms of three years, and

"(B) three shall be appointed for terms of two years, as designated by the President at the time of appointment.

"(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

"(c) CHAIRMAN.—The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

"(d) MEETINGS.—(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

"(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

ATTACHMENT

Form 8-66 163a

PUBLIC LAW 95-622—NOV. 9, 1978

92 STAT. 3439

"(e) COMPENSATION.—(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

"(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5 of the United States Code.

5 USC 5332.

"DUTIES OF THE COMMISSION"

"SEC. 1802. (a) STUDIES.—(1) The Commission shall undertake studies of the ethical and legal implications of—

42 USC 300v-1.

"(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

"(B) the matter of defining death, including the advisability of developing a uniform definition of death;

"(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

"(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

"(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information contained in such records, and

"(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

"(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this title on its own initiative or at the request of the head of a Federal agency.

"(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

"(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and shall submit a recommendation in the report applies.

Report to President and Congress.

"(b) **RECOMMENDATIONS TO AGENCIES.**—(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

"(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

"(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

"(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

"(c) **REPORT ON PROTECTION OF HUMAN SUBJECTS.**—The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

"(d) **ANNUAL REPORT.**—Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) made to Federal agencies by the Commission during the fiscal year and the actions taken, pursuant to subsection (b)(2), by the agencies upon such recommendations, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

"(e) **PUBLICATIONS.**—The Commission may at any time publish and disseminate to the public reports respecting its activities.

"(b) **DEFINITIONS.**—For purposes of this section:

"(1) The term 'Federal agency' means an authority of the government of the United States, but does not include (A) the Congress, (B) the courts of the United States, and (C) the government of the Commonwealth of Puerto Rico, the government of the District of Columbia, or the government of any territory or possession of the United States.

"(2) The term 'protection of human subjects' includes the protection of the health, safety, and privacy of individuals.

"ADMINISTRATIVE PROVISIONS"

"SEC. 1803. (a) **HEARINGS.**—The Commission may, for the purpose of carrying out this title hold such hearings, sit and act at such times

and places, take such testimony, and receive such evidence, as the Commission may deem advisable.

"(b) **STAFF.**—(1) The Commission may appoint and fix the pay of such staff personnel as it deems desirable. Such personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

"(2) The Commission may procure temporary and intermittent services to the same extent as is authorized by section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule.

"(3) Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist it in carrying out its duties under this title.

"(c) **CONTRACTS.**—The Commission, in performing its duties and functions under this title, may enter into contracts with appropriate public or nonprofit private entities. The authority of the Commission to enter into such contracts is effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

"(d) **INFORMATION.**—(1) The Commission may secure directly from any Federal agency information necessary to enable it to carry out this title. Upon request of the Chairman of the Commission, the head of such agency shall furnish such information to the Commission.

"(2) The Commission shall promptly arrange for such security clearances for its members and appropriate staff as are necessary to obtain access to classified information needed to carry out its duties under this title.

"(3) The Commission shall not disclose any information reported to or otherwise obtained by the Commission which is exempt from disclosure under subsection (a) of section 552 of title 5, United States Code, by reason of paragraphs (4) and (6) of subsection (b) of such section.

"(c) **SUPPORT SERVICES.**—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

"AUTHORIZATION OF APPROPRIATIONS; TERMINATION OF COMMISSION"

"SEC. 1804. (a) **AUTHORIZATIONS.**—To carry out this title there are authorized to be appropriated \$5,000,000 for the fiscal year ending September 30, 1979, \$5,000,000 for the fiscal year ending September 30, 1980, \$5,000,000 for the fiscal year ending September 30, 1981, and \$5,000,000 for the fiscal year ending September 30, 1982.

"(b) **FEDERAL ADVISORY COMMITTEE ACT; TERMINATION.**—The Commission shall be subject to the Federal Advisory Committee Act, except that, under section 14(a)(1)(B) of such Act, the Commission shall terminate on December 31, 1982."

MISCELLANEOUS PROVISIONS

42 USC 300v
note.

Sec. 302. (a) The President shall initially appoint members to the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (established under the amendment made by section 301) not later than 90 days after the date of the enactment of this title.

Repeal.
42 USC 2091-1
note.
42 USC 218.

(b) Effective November 1, 1978, part A of title II of the National Research Act, section 213 of such Act, and subsection (f) of section 217 of the Public Health Service Act are repealed.

Approved November 9, 1978.

LEGISLATIVE HISTORY:

HOUSE REPORT No. 95-1192 accompanying H.R. 12347 (Comm. on Interstate and Foreign Commerce).

SENATE REPORT No. 95-838 (Comm. on Human Resources).
CONGRESSIONAL RECORD, Vol. 124 (1978):

18 MAR 1980

MEMORANDUM FOR: Deputy Director, National Foreign
Assessment Center
Deputy Director for Operations
Deputy Director for Science and Technology
General Counsel

FROM : Don I. Wortman
Deputy Director for Administration

SUBJECT : Agency Task Force in Support of Liaison
With the President's Commission for the
Study of Ethical Problems in Medicine and
Biomedical and Behavioral Research

25X1 1. In accordance with the establishment of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research by an executive order issued by President Carter on 17 December 1979, and in accordance with Title III Section 301 of Public Law 95-622, [REDACTED], of the Office of Medical Services has been designated as liaison officer between the Central Intelligence Agency and the Commission.

25X1 2. To assist [REDACTED] in his liaison with the President's Commission, I propose the organization of an Agency task force consisting of a representative from the Office of General Counsel and from each Directorate. [REDACTED] 25X1 would serve as the first chairman of the task force with periodic rotation among the other members during the tenure of the Commission.

3. As a first order of business, the task force should consider the Agency's experience with respect to the incidence of research-related injuries and existing policies and guidelines relating to the provision of compensation for such injuries in preparation for a response to the Commission by 1 May 1980, as requested.

4. Please provide [redacted] with the name of your designated member of the task force by the close of business 21 March 1980.

25X1

25X1

[redacted]
Don I. Wortman

Attachments:

- A. Ltr to DCI from Chairman, President's Commission
- B. Title III Section 301 of Public Law 95-622